

Docket No. 217941US0PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Chiara MALVOLTI, et al.

SERIAL NO: 10/030,101

GAU: 1616

FILED: May 3, 2002

EXAMINER: HAGHIGHATIAN, M.

FOR: FORMULATIONS OF STEROID SOLUTIONS FOR INHALATORY ADMINISTRATION

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☒ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- ☒ Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- ☒ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION


- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Frederick D. Vastine, Ph.D.

Registration No. 27,013

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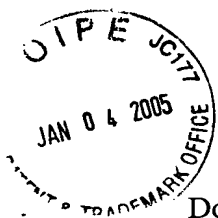
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11/05/2005 NROCHA1 00000001 10030101

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180.00 OP



LIST OF RELATED CASES

<u>Docket Number</u>	<u>Serial or Patent Number</u>	<u>Filing or Issue Date</u>	<u>Patent Appl. Publication No.</u>	<u>Inventor/ Applicant</u>
*217941US0 PCT	10/030,101	05/03/02		MALVOLTI et al
208858US0 PCT	09/831,888	07/19/01		LEWIS et al
04158-0014-0 PCT	09/147,669	02/24/99		LEWIS et al

*Present Application; listed for information

Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 217941US0PCT		SERIAL NO. 10/030,101	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Chiara MALVOTI, et al.			
				FILING DATE May 3, 2002		GROUP 1616	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	6,290,930	09/18/01	Frank E. BLONDINO et al			
	AB	2003/0190287 A1	10/09/03	David LEWIS et al			
	AC	2003/0206870 A1	11/06/03	David LEWIS et al			
	AD	5,653,961	08/05/97	Rebecca A. McNALLY et al			
	AE	6,451,285	09/17/02	Frank E. BLONDINO et al			
	AF	2003/0077230 A1	04/24/03	Frank E. BLONDINO et al			
	AG	6,645,466	11/11/03	Manfred KELLER et al			
	AH	6,149,892	11/21/00	Ignatius Loy BRITTO			
	AI	5,695,743	12/09/97	Tarlochan S. PUREWAL et al			
	AJ	5,683,677	11/04/97	Tarlochan S. PUREWAL et al			
	AK	6,026,808	02/22/00	Thomas Alex ARMER et al			
	AL	6,045,778	04/04/00	Paul Donald JAGER et al			
	AM	2001/0031244 A1	10/18/01	David LEWIS et al			
	AN	6,006,745	12/28/99	Paul E. MARECKI et al			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO		
	AO	WO 98/56349	12/17/98	WIPO			
	AP	WO 98/34595	08/13/98	WIPO (w/English Abstract)			XXX
	AQ	WO 92/11236	07/09/92	WIPO			
	AR	WO 96/32150	10/17/96	WIPO			
	AS	WO 96/32151	10/17/96	WIPO			
	AT	WO 96/32345	10/17/96	WIPO			
	AU	WO 95/17195	06/29/95	WIPO			
	AV	0 504 112 A2	09/16/92	EPO (w/English Abstract)			XXX
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AW	R.O. Williams III et al, "A study of an epoxy aerosol can lining exposed to hydrofluoroalkane propellants", <u>EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS</u> , Vol. 44, pp. 195-203, (1997).					
	AX	<u>ABPI COMPENDIUM OF DATA SHEETS AND SUMMARIES OF PRODUCT CHARACTERISTICS</u> , Datapharm Publications Limited, London, pp. 81-82, (1996-97).					
	AY	Paul A. Sanders, Ph.D., "Homogeneous Systems and Their Properties", <u>HANDBOOK OF AEROSOL TECHNOLOGY</u> , Second Edition, Van Nostrand Reinhold Company, NY, pg. 30, 1979.					
	AZ	G. Brambilla et al, "Modulation of Aerosol Clouds Produced by HFA Solution Inhalers", <u>PORTABLE INHALERS</u> , pp. 155-159, (November 26 & 27, 1998).				<input type="checkbox"/> Additional References sheet(s) attached	
Examiner					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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<div style="border: 1px solid black; border-radius: 50%; padding: 10px; display: inline-block; text-align: center;"> PIPE <small>OFFICE OF REFERENCES CITED BY APPLICANT</small> JAN 04 2005 </div>				APPLICANT Chiara MALVOTI, et al.			
				FILING DATE May 3, 2002		GROUP 1616	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	BA	5,954,047	09/21/99	Thomas Alex ARMER et al			
	BB	5,435,297	07/25/95	Christoph KLEIN			
	BC	3,361,306	01/02/68	W. M. GRIM			
	BD	3,622,053	11/23/71	John V. RYDEN			
	BE	2003/0157028 A1	08/21/03	David LEWIS et al			
	BF	2003/0190289 A1	10/09/03	David LEWIS et al			
	BG	4,835,145	05/30/89	Peter MacDONALD			
	BH	5,676,930	10/14/97	Paul D. JAGER			
	BI	6,413,496	07/02/02	Michael GOODMAN et al			
	BJ	5,642,728	07/01/97	Jan ANDERSSON et al			
	BK	5,415,853	05/16/95	Helmut HETTCHE et al			
	BL	5,605,674	02/25/97	Tarlochan S. PUREWAL et al			
	BM	6,315,985	11/13/01	Zheng Z. WU et al			
	BN	6,131,566	10/17/00	Ian Carl ASHURST			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO		
	BO	WO 93/05765	04/01/93	WIPO			
	BP	WO 93/18746	09/30/93	WIPO (w/English Abstract)			XXX
	BQ	WO 94/21229	09/29/94	WIPO			
	BR	WO 93/11743	06/24/93	WIPO			
	BS	WO 98/01147	01/15/98	WIPO			
	BT	WO 98/13031	04/02/98	WIPO			
	BU	WO 00/35458	06/22/00	WIPO			
	BV	WO 00/78286	12/28/00	WIPO			
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	BW	B. Meakin, "Fine Particle Dose Control of Solution Based pMDIs", <u>DRUG DELIVERY TO THE LUNGS IX</u> , The Aerosol Society, pp. 1-20, (December 14 & 15, 1998).					
	BX	Chet Leach, "Enhanced Drug Delivery Through Reformulating MDIs with HFA Propellants-Drug Deposition and Its Effect on Preclinical and Clinical Programs", <u>Respiratory Drug Delivery V</u> , 1996, pp. 133-144.					
	BY	L. Harrison et al, "Twenty-eight-day Double-blind Safety Study of an HFA-134a Inhalation Aerosol System in Healthy Subjects", <u>J. Pharm. Pharmacol.</u> , 1996, Vol. 48, pp. 596-600.					
	BZ	P. Hoet et al, "Epidemic of liver disease caused by hydrochlorofluorocarbons used as ozone-sparing substitutes of chlorofluorocarbons", <u>The Lancet</u> , 1997, Vol. 350, pp. 556-559.				<input type="checkbox"/> Additional References sheet(s) attached	
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U.S. PATENT DOCUMENTS								
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
	CA	2004/0047809 A1	03/11/04	David LEWIS et al				
	CB	5,891,419	04/06/99	Anthony J. CUTIE				
	CC	5,192,528	03/09/93	R. RADHAKRISHNAN et al				
	CD	4,185,100	01/22/80	David T. ROVEE et al				
	CE	6,253,762	07/03/01	Ignatius Loy BRITTO				
	CF	6,713,047	03/30/04	David LEWIS et al				
	CG	2003/0066525	04/10/03	David LEWIS et al				
	CH	6,716,414	04/06/04	David LEWIS et al				
	CI	2004/0062720	04/01/04	David LEWIS et al				
	CJ	2004/0096399	05/20/04	David LEWIS et al				
	CK	4,499,108	02/12/85	Joel A. SEQUEIRA et al				
	CL	5,955,058	09/21/99	Paul Donald JAGER et al				
	CM	6,150,418	11/21/00	Dieter HOCHRAINER et al				
	CN	6,143,277	11/07/00	Ian ASHURST et al				
FOREIGN PATENT DOCUMENTS								
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	CO	WO 99/65460	12/23/99	WIPO				
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	CQ	WO 98/24420	06/11/98	WIPO				
	CR	0 372 777	06/13/90	EPO				
	CS	0 911 048	04/28/99	EPO				
	CT	WO 99/12596	03/18/99	WIPO				
	CU	WO 92/20391	11/26/92	WIPO				
	CV	WO 98/03533	01/29/98	WIPO				
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)								
	CW	J. Daly, Jr., "Properties and toxicology of CFC alternatives", <u>Aerosol Age</u> , February 1990, pp. 26-27, 40, 56 and 57.						
	CX	D. Strobach, "Alternatives to CFCs" Part II, <u>Aerosol Age</u> , July 1988, pp. 32-33, 42 and 43						
	CY	Tsi-Zong Tzou et al, "Drug Form Selection in Albuterol-Containing Metered-Dose Inhaler Formulations and Its Impact on Chemical and Physical Stability", <u>Journal of Pharmaceutical Sciences</u> , 1997, Vol. 86, No. 12, pp. 1352-1357.						
	CZ	M.J. Kontny et al, "Issues Surrounding MDI Formulation Development with Non-CFC Propellants", <u>Journal of Aerosol Medicine</u> , 1991, Vol. 4, No. 3, pp. 181-187.				<input type="checkbox"/> Additional References sheet(s) attached		
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	DA	6,045,784	04/04/00	Nicholas Arthur RUEBUSCH et al			
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	DS	WO 00/30608	06/02/00	WIPO			
	DT	WO 00/53157	09/14/00	WIPO			
	DU	WO 97/47286	12/18/97	WIPO			
	DV	2 326 334	12/23/98	GB			
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	DW	I. P. Tansey, "Changing to CFC-Free Inhalers: The Technical and Clinical Challenges", <u>The Pharmaceutical Journal</u> , 1997, Vol. 259, pp. 896-898.					
	DX	D. Tiwari et al, "Compatibility Evaluation of Metered-Dose Inhaler Valve Elastomers with Tetrafluoroethane (P134a), a Non-CFC Propellant, <u>Drug Development and Industrial Pharmacy</u> , 1998, Vol. 24, No. 4, pp. 345-352.					
	DY	<u>Handbook of Pharmaceutical Excipients</u> , 3rd Ed., Kibbe Editor, pp. 7-9, 220-222, 234-235 and 560-561.					
	DZ	L. I. Harrison et al, "Pharmacokinetics and Dose Proportionality of Beclomethasone From Three Strengths of A CFC-Free Beclomethasone Dipropionate Metered-Dose Inhaler", <u>Biopharmaceutics & Drug Disposition</u> , 1997, Vol. 18, No. 7, pp. 635-643.				<input type="checkbox"/> Additional References sheet(s) attached	
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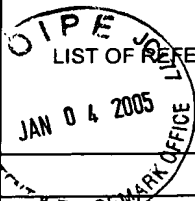
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	EA						
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FOREIGN PATENT DOCUMENTS

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	EO	0 653 204	05/17/95	EPO		
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	EQ	WO 91/11173	08/08/91	WIPO		
	ER	WO 93/11747	06/24/93	WIPO		
	ES	WO 94/21228	09/29/94	WIPO		
	ET	WO 96/18384	06/20/96	WIPO		
	EU	WO 96/19198	06/27/96	WIPO		
	EV	WO 96/19968	07/04/96	WIPO		

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

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	EX	
	EY	
	EZ	<input type="checkbox"/> Additional References sheet(s) attached

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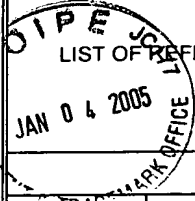
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	FL						
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FOREIGN PATENT DOCUMENTS

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	FR	WO 94/13262	06/23/94	WIPO		
	FS	WO 00/06121	02/10/00	WIPO (w/English Abstract)		XXX
	FT	WO 99/65464	12/23/99	WIPO		
	FU					
	FV					

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	FW	
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	FZ	<input type="checkbox"/> Additional References sheet(s) attached

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